ZIMMER BIOMET

URGENT MEDICAL DEVICE RECALL NOTICE
February 16, 2016

Verso Shoulder Forked Retractor (Comprehensive Instrumentation 2 Prong Retractor)
Part Number: 402852
Lots: all

Dear Risk/Recall Manager,

This notification is to inform you of an Urgent Medical Device Recall initiated by Zimmer Biomet which involves **PN: 402852 Verso Shoulder Forked Retractor (Comprehensive Instrumentation 2 Prong Retractor)**. All lots are affected by this recall. The legal manufacturer of this product is Biomet Inc.

These instruments have been further consigned to your facility by a Zimmer Biomet distributor. Zimmer Biomet has initiated this action following an investigation which identified that PN: 402582 was manufactured using 420 stainless instead of the material specified on the print, 420 S29 stainless steel. 420 stainless is more brittle than 420 S29.

The instrument may fracture during use.

If the retractor fractures during surgery, surgical intervention may be necessary to retrieve any fractured pieces. A delay in surgery greater than 30 minutes may occur.

If the pieces are unable to be retrieved, the patient would retain a foreign body.

This action requires the immediate location and discontinued use of the product and its return to Zimmer Biomet.

The following actions are **REQUIRED**:

- ✓ Immediately locate and remove the identified device(s) listed below from circulation.
- ✓ Your Zimmer Biomet sales representative will remove the affected product from your facility.
- ✓ Review this notification and ensure that all affected personnel are aware of its contents.
- ✓ Carefully follow the instruction on the enclosed **"Certificate of Acknowledgment"** and email a copy to CPWARFieldAction@zimmerbiomet.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call (800)FDA-1088

Mailing Address:
P.O. Box 587
Warsaw, IN. 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Fax: 574-372-1683
www.zimmerbiomet.com

Shipping Address:
56 E Bell Drive
Warsaw, IN 46582

ZIMMER BIOMET

URGENT MEDICAL DEVICE RECALL NOTICE
February 16, 2016

Thank you in advance for your assistance and prompt attention. On behalf of Zimmer Biomet, I apologize for any inconvenience this may cause. Questions related to this notice should be directed to (574) 372-1570, Monday through Friday, 8 a.m. to 5 p.m.

Sincerely,

Audrey Daenzer
Field Action Specialist
audrey.daenzer@zimmerbiomet.com

Mailing Address:
P.O. Box 587
Warsaw, IN. 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Fax: 574-372-1683
www.zimmerbiomet.com

Shipping Address:
56 E Bell Drive
Warsaw, IN 46582

ZIMMER BIOMET

URGENT MEDICAL DEVICE RECALL NOTICE
February 16, 2016

Certificate of Acknowledgement

ATTENTION: Audrey Daenzer, Field Action Specialist

Email: CPWARFieldAction@zimmerbiomet.com

Regulatory Action: **URGENT MEDICAL DEVICE RECALL NOTICE**

Description: **Verso Shoulder Forked Retractor**
(Comprehensive Instrumentation 2 Prong Retractor)

By signing the below, I acknowledge that the required actions have been taken in accordance with the Urgent Medical Device Recall Notice.

Printed Name: _____ Title: _____

Facility Name: _____

Facility Address: _____

Telephone: _____

Signature: _____ Date: _____

Mailing Address:
P.O. Box 587
Warsaw, IN. 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Fax: 574-372-1683
www.zimmerbiomet.com

Shipping Address:
56 E Bell Drive
Warsaw, IN 46582